K091295

MAY 1 5 2009

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification Aplio™ XG (v4.0) SSA-790A Ultrasound System

510(k) Summary

Submitter's Name:

Toshiba America Medical Systems, Inc.

Address:

PO Box 2068, 2441 Michelle Drive Tustin, CA 92781-2068

Contact:

Paul Biggins, Director Regulatory Affairs

Telephone No.:

(714) 730-5000

Device Proprietary Name:

APLIO XG MODEL SSA-790A Version 4.0

Common Name:

Diagnostic Ultrasound System

Classification:

Regulatory Class: IIReview Category: Tier II

Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN
 [Fed. Reg.No.: 892.1550]

Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO

[Fed. Reg.No.: 892.1560]

Diagnostic Ultrasonic Transducer – Product Code: 90-ITX

[Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to:

Toshiba Ultrasound Diagnostic System Aplio XG MODEL SSA-790A V3.0 - 510(k) K082119

Device Description:

The Aplio XG v4.0 is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Intended Use:

The Aplio v4.0 is intended to be used for the following type of studies: fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular and musculo-skeletal (both conventional and superficial).

Safety Considerations:

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-1 (applicable portion), IEC 60601-1-2 (applicable portion), IEC 60601-1-4 (applicable portion), IEC 60601-2-37 (applicable portions), IEC 62304 (applicable portion) and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.



MAY 1 5 2009

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Toshiba America Medical Systems, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

Re: K091295

Trade/Device Name: APLIO XG Diagnostic Ultrasound System, Model SSA-790A version 4.0

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: May 1, 2009 Received: May 4, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the APLIO XG Diagnostic Ultrasound System, Model SSA-790A version 4.0, as described in your premarket notification:

Transducer Model Number

- <u>PST-25BT</u>	<u>PVT-375MV</u>	<u>PVT 661VT</u>
PST-30BT	PET-382BT	PVT-681MV
PST-50AT	<u>PVT-382MV</u>	PVT-745BTV
PST-65AT	<u>PVT-575MV</u>	PVT-770RT
<u>PVT-375BT</u>	<u>PVT-674BT</u>	PLT-604AT

PLT-704AT	PLT-1202S	<u>PLT-1204MV</u>
PLT-704SBT	PLT-1204AT	<u>PET-510MB</u>
PLT-705BTH	PLT-1204BT	<u>PC-20M</u>
PLT-705BTF	PLT-1204AX	<u>PC-50M</u>
PLT-805AT	PLT-1204BX	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,

Janine M. Morris

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices Office of Device Evaluation

Center for Devices and Radiological Health.

Enclosure(s)

System:	<u>Aplio</u>	<u>XG</u>	<u>v4.0</u>	<u>SSA</u>	<u>-790A</u>
Transduc	cer:				

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Specific	В	M	PWD	CWD	Celor	Combined	THI	Dynamic	Power	CHI	4D	Other
(Tracks 3)	:		!		Doppler	(Specify)		Flow		2D		[Note]
)phthalmic	-)	·		·							pr: r.q.19, m m.p	1
Fetal	Р	P	P	P	P	2	Р	P	P	P	P	5,7,8,9,10
Abdominal	Р	' P	Р	P	P	2,3	P	. P	Р	Р	Р	5,7,8,9,10
Intra-operative (Abdominal)	. P	. P	P		P	2	Р	P	P			4,5
Intra-operative (Neuro)							.					
Laparoscopic	,		1	•	· · · · · · · · · · · · · · · · · · ·		 !					1
Pediatric	P	P	; P	P	Р	2.3	P	Р	P	. P	P	5,7,8,9,10
Small Organ (Note 1)	; P	P	P		Р	2	P	P	P			4.5,6,7,9
Neonatal Cephalic	Р	; p	P	P	P	3	P	P	P	Р		1
Adult Cephalic	Р	P	Р	P	P	3	P	P	P	Р		of one or
Trans-rectal	P	P	, P		. P	2	Р	P	P	P :	, - P	4,5,7
Trans-vaginal	· P	وا	Р		P	2	Р	Р	P	P	Р	4,5,7
Trans-urethral	· · · · · · · · · · · · · · · · · · ·			1		**		· . · · · · · · · · · · · · · · · · · ·				1
Trans-esoph, (non-Card.)	- ja	L	;					- Mannessa	AP (.			1
Musculo-skeletal (Conventional)	P	i P	. P		P	: 2	Р	P	Р	. Р		4,5,6,7,9
Musculo-skeletal (Superficial)	P	! p	P	; " !	P	2	Ρ̈́	P	P	: P	• <i></i>	4,5,6,7,9
Intravascular										. :	<i>-</i>	al and destruited
Other (Specify)		••••						÷	:-			
Cardiac Adult	P	P	Р	. P	P	. 3	P	Р	P	Р		. 4
Cardiac Pediatric	P	P	. P	P	P	3	. P	P	р	. P		4
Intravascular (Cardiac)							:	agenta anno commo de mante. L				
Trans-esoph. (Cardiac)	P	Р	Ь	P	þ	3	Р				*** ***	4
Intra-cardiac			Y	1			::::::::::::::::::::::::::::::::::::::		Baradad a cardenia a Problem a com			
Other (Specify)			:	7				il T	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		,	
Peripheral vessel		,	:	:		*******				·		
	P	P	, Р	i P	P	2	P	į P	, P	P		4,5.6,7,9
				1	!				-		_	

N = new indication; P = previously cleared by FDA: E = added under this appendix Previous 510(k) of the transducer: K082119

N	ote	1	Smal	organ	incl	udes	thyroid,	breast	and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M: B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign Off)

Division of Reproductive, Abdominal and

Radiological Devices

Transducer: PST-25BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operat	ion								
Specific (Tracks 3)	В	M	PWD	CWD		Combined (Specify)		Dynamic Flow	Power	CHI 2D	4D	Other Note
phthalmic												town that within
Fetal	₩¢								,			
Abdominal	P	P	; P	Р	P	3	Р	P	P	: P		
Intra-operative (Abdominal)				:							1	
Intra-operative (Neuro)						. ,		T TE	;		·	,
Laparoscopic				7' '		7	• • • • •			:		
Pediatric	P	Р	P	Р	P	3	P	P	P	Р		
Small Organ (Note 1)	,					i		!	:	1		
Neonatal Cephalic	Р	P	P	Р	P	- 3	Р	P	Р	. P	1	
Adult Cephalic	P	P	P	P	P	. ·3	P	P	Р	Р		
Frans-rectal	,	,			:	1	,	;	,		:	
Frans-vaginal					í	1					ľ	
Frans-urethral						and a recovery and a						
Frans-esoph. (non-Card.)				1					!	:		
Musculo-skeletal						į		i i	!		!	
(Conventional)		٠.				1		2	ļ		; ;	J
Musculo-skeletal (Superficial)							-		<u> </u>	·	i	
Intravascular								7				
Other (Specify)		:						.i		·,		
Cardiac Adult	P	<u></u> -	<u></u>		P	3	P	P	P	<u> P</u> .	i	4
Cardiac Pediatric	P	. Р	P	P	P		. P	; P	Р.	P		4
Intravascular (Cardiac)					: :						:	
Frans-esoph. (Cardiac)									<u>.</u>		· · · · · · · · · · · · · · · · · · ·	
ntra-cardiac						<u> </u>	<u>.</u>	:		ļ	·	
Other (Specify)								v	<u>.</u>		£ .	
Peripheral vessel	•		•		í			•			;	
					;				;			

N = new indication; P = previously	cleared by FDA; E =	added under	this appendix
Previous \$100k) of the transducers	MU63110		

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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

Transducer: PST-30BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Opera	ion								
Specific (Tracks 3)	В	M	PWI			Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal			: "									
Abdominal	P	P	P	P	P	3	Р	Р	P	Р	ĺ	-
Intra-operative (Abdominal)			.		, +1	7		1				:
Intra-operative (Neuro)	•••									,		
Laparoscopic				/			,	•				i
Pediatric	Р	Р	P	Р	Р.	3	Р	Р	Р	P		
Small Organ (Specify) (1)												
Neonatal Cephalic	Р	P	P	P	Р	3	P	P	Р	P		
Adult Cephalic	Р	P	P	. Р	P	3	P	P	P	P		
Trans-rectal						, ar riseas		region on the comment				** ***
Trans-vaginal	-								1		:	
Trans-urethral							· · · · · · · · · · · · · · · · · · ·	T			- · ·	
Trans-esoph. (non-Card.)	*						i	-}	<u>.</u>			<i>†</i>
Musculo-skeletal							:	T				
(Conventional)												
Musculo-skeletal (Superficial)						1				•		:
Intravascular	;	_									•	
Other (Specify)			•			• • • • • • • • • • • • • • • • • • • •		:				• •
Cardiac Adult	P	Р	P	P	P	3	Р	P	Р	Р		4
Cardiac Pediatric	P	: P	P	P	P	3	P	Р	P	Р		4
Intravascular (Cardiac)		*** * *					:					
Trans-esoph. (Cardiac)			Ŧ .		•			1		•	•	: "
Intra-cardiac				3					in an exemple of I	• •	gree en	:
Other (Specify)				,								
Peripheral vessel												•
		:	:					1	•			
		:			. ,, -							
Other (Specify)		•							1			

N = new	indication; P	= previously	cleared b	y FDA;	E = added	under thi	s appendix
Previous	S10(k) of the	transducer: I	K082119				

Note	1 Small	Argan	includes	thyroid	breast	and	testicle
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Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

Division of Reproductive, Abdominal and

Radiological Devices

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Transducer: PST-50AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of (Operat	ion								
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
phthalmic		ļ }		:		General contract of the cont						
Fetal		,										, 1,1 ,021,0
Abdominal						:	•			:		
Intra-operative (Abdominal) Intra-operative (Neuro)	: .					• · · · · · · · · · · · · · · · · · · ·						
Laparoscopic					aladas an yang sasa yan	and and an array		•		· · · · · ·		1 *** * * *
Pediatric		1										
Small Organ (Note 1)	. i			···					<u>.</u>	t		
Neonatal Cephalic	. P	: P	Ρ	∴ P	P	3	P .				,	
Adult Cephalic										: :		
Frans-rectal	*.	•		•							:	
Frans-vaginal				! .		, , ,		1		}	1	,
Trans-urethral	,	1			•			7 7			;	
Frans-esoph. (non-Card.)					and the final of the second	,	NEIN			1	:	
Musculo-skeletal					•			: "			į	7
(Conventional)				*		g				}	, V	
Musculo-skeletal (Superficial)									• 	i 1	:	
Intravascular							,		,		,	
Other (Specify)	-						,	;			-	• • •
Cardiac Adult	þ	P	Р	P	Р	3	Р				···· ••• • • • • • • • • • • • • • • •	4
Cardiac Pediatric	Р	P	. Р	. P	P	3	P	·			· · · · ·	4
ntravascular (Cardiac)						:				į., .		
Frans-esoph. (Cardiac)										:) 	
ntra-cardiac			·	إحد سحان		.,			<u> </u>	·	i	
Other (Specify)											!	
Peripheral vessel			:					, , ,			:	
	· •					•		•				
		-		1					:	:		

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

System:	Aplio XG v4.0 SSA-790A
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Transducer: PST-65AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Specific	В	M	PWD CWD	Color	Cambinad	THE	Dynamic	DALUA"	CHI	3D	Other
(Tracks 3)	U	(41	·	Doppler	(Specify)	4111	Flow	TAMEL	2D	<i>J</i>	[Note]
phthalmic			dan a	i					 		Ī
Fetal					,						:
Abdominal			:								
Intra-operative (Abdominal) Intra-operative (Neuro)					40 4 40.						
Laparoscopic	····				·				i —		 :
Pediatric									:: 		
Small Organ (Note 1)		-,					;	artir (/w 2004000 mm.
Neonatal Cephalic	P	P	PP	Р.	÷	P	, P	P	· · · · · · · · · · · · · · · · · · ·		
Adult Cephalic		•	:						j		
Trans-rectal		• "		· · · · · · · · · · · · · · · · · · ·			fee in the makes				
Trans-vaginal					····				(
Trans-urethral	***				**			-			:
Trans-esoph. (non-Card.)			-j- 10		· · · · · · · · · · · · · · · · · · ·						
Musculo-skeletal (Conventional)			· · ·				:				İ
Musculo-skeletal (Superficial)			• •			• • •) , ,		
Intravascular		;- · · · ·				• • •		- 17.77 f 17 m make	٠ ، ،		
Other (Specify)		,			,	•			1		
Cardiac Adult	Р	P	P P	P	3	Р	Р	P			: 4
Cardiac Pediatric	P	P	PP	Р	3	P	P	, P	<u> </u>	<u>.</u>	4
Intravascular (Cardiac)	•								* · · · · · · · · · · · · · · · · · · ·		
Trans-esoph. (Cardiac)									1	·	
Intra-cardiac									-		Tria (Servi)
Other (Specify)		·					·; · ·-				
Peripheral vessel			***** * ***** ** ***		* ***********	• • • • •	· • · · · · · · · · · · · · · · · · · ·		.)		
		i.	:		:			! ,	;		
									N.		

N = new indication; P = previously cleared by	y FDA: E = added under this appendix
Previous 510(k) of the transducer: K082119	

Note 1 Small organ includes thyroid, breat	at and	testicle
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD: BDF/MDF: BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF: BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

Prescription Use Only (Per 21 CRF801.109) 510(k) Number _

<u>1007129</u>

System:	Aplio XG v4.0 SSA-790A
_	

Transducer: PVT-375BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operation								
Specific (Tracks 3)	В	М	PWD CWD		Combined (Specify)	тні	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
)phthalmic					<u>.</u>		1				•
Fetal	Р	P	P	P	2	P	i p	Р	P		5, 7
Abdominal	Р	P	P	Р	2	P	, P	Р	Р		5;7
Intra-operative (Abdominal)					7				1		1
Intra-operative (Neuro)						••		. ,			·
Laparoscopic							*:			******)* -
Pediatric	Р	Р	P	. P	. 2	Р.	: P	Р	P		5, 7
Small Organ (Specify) (1)			1			**************************************	1		~- ···· , · · · · · · · · · · · · · · · ·		ny na maria an :
Neonatal Cephalic	,	-							1	,	: <u>-</u>
Adult Cephalic					· · · · · · · · · · · · · · · · · · ·		i				
Trans-rectal			F F F F F F F F F F F F F F F F F F F	D7 4544 - 4444	7		:				÷
Trans-vaginal							5" "	***	T		
Trans-urethral	···· ·		ده و استفاد منظ الکتاب ا					• • • • •	- ·	, ,	
Trans-esoph. (non-Card.)			. M. 4,47 mbb) — av. mb . F. s. comb								i
Musculo-skeletal	• • • • •										
(Conventional)	'		1				i			į	:
Musculo-skeletal (Superficial))			:			1			, . 	
Intravascular		•					******				
Other (Specify)											
Cardiac Adult					-;				,	· · · · · · · · · · · · · · · · · · ·	
Cardiac Pediatric									· ·		
Intravascular (Cardiac)		•		***			3		•		:
Trans-esoph. (Cardiae))			1	
Intra-cardiac			s to operate to	eren i i	>>=====================================	•	energe and a comment.		P 70		
Other (Specify)		-					migro en de pare		• · · · · · · · · · · · · · · · · · · ·		A
Peripheral vessel	:			** * **				 		·,- · · · · · · ·	·
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N = new indication; $P = previously cleared by FDA$; $E = addec$	d under this appendix
Previous 510(k) of the transducer: K082119	

X1-4-	1	Caralli		includes	الدائم سيبلم	1	تعديم لا سد	.1.
NOTE	1	Sman	organ.	includes	unyroid.	preast :	ano testi	cie.

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Transducer: PVT-375MV

intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	: B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D		Other [Note]	
Ophthalmic	.10-138165-5641	.i (! !	· · · · · · · · · · · · · · · · · · ·	-				<u> </u>		15 -24 Martin (Michael)	
Fetal	: N	. N	N		. N	2	. N	N	N	N	N	5,7,8,9,10	
Abdominal	· N	N	N	1	N	2	N	N	N	Ν	N	5,7,8,9,10	
Intra-operative (Abdominal)										i			
Intra-operative (Neuro)		*]/ • •				' <u>.</u> ,	· · · · :		\$1	
Laparoscopic		~ ~-]- • :	e en e eve en el F	*****		 -	ija marandi I			
Pediatric	N	N	N	:	N	2	N	N	N	N	N	5,7,8,9,10	
Small Organ (Specify) (1)					a	eta e servicia e servicia.						e je er û ser kurdise ûne e.	
Neonatal Cephalic		v 1 - 1								:		} • • • · ·	
Adult Cephalic						1				· · · · · · · · · · · · · · · · · · ·	:		
Frans-rectal	4	. -	200 - 1 100	; qualitation p. 2		**** 4 - * ** *		.]		q=	٠		
Frans-vaginal	. ,		****						<u>-</u>		r - -		
Frans-urethral			4 1:0 - 0*0	j :				· ······ · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	<u> </u>		7	
Frans-esoph. (non-Card.)		3		1.1 mm m		- Constant of Ar							
Musculo-skeletal	• • •		•						· '	;			
(Conventional)			*		1					i ,			
Musculo-skeletal (Superficial)					l					1			
ntravascular													
Other (Specify)			*** * ** * * * * * * * * * * * * * * * *										
Cardiac Adult													
Cardiac Pediatric		٠.			1								
ntravascular (Cardiac)													
Trans-esoph. (Cardiac)								, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		:			
ntra-cardiac				7 7" 47 ·				* ** *** - * * * * * * *			· · · · · · · · · · · · · · · · · · ·		
Other (Specify)	,		,							•	 !		
Peripheral vessel											-		
		:		1								1	
Moranis responsible to the second of the sec				ay amenda a gayaya sa	n 1 Flore - Lichtophage e	eşibiyeli deşançık er i	, , ,	No in the control of			: :		
Other (Specify)													

N = new indication; P = previously cleared by FDA: E = added under this appendix Previous 510(k) of the transducer: K082119

Note 1	Small	organ	includes	thyroid	breast and	testicle
1,000	Dilliamit	OLEGII	THORITICS	CIL YI O I CI.	OLCASE ALIC	COULT.

Note 4 TD!

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

System:	Aplio XG v4.0 SSA-790A

Transducer: PET-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	water of concession		Operation							T - 64 Febru	
Specific (Tracks 3)	В	M	PWD CWD		Combined (Specify)		Dynamic Flow	Power	CHI 2D	3D	Other [Note]
phthalmic		******			i	14 F 44 C 4 (1444)				det de pres	1
Fetal	Р	Ρ	P	P	2	P	P	P	P	-44	5
Abdominal	P	P	• P	Р	2	Р	, P	P	P		; 5
Intra-operative (Abdominal) Intra-operative (Neuro)					t						
Laparoscopic					** ,			. 1			1
Pediatric	; P	P	P	j	2	P ^	P	P	Р		5
Small Organ (Specify) (1)	1 1111		· · · · · · · · · · · · · · · · · · ·	• • •				i) :
Neonatal Cephalic											
Adult Cephalic		•	' '		:						• •
Frans-rectal											
Frans-vaginal	, -						· · · · · ·				!
Frans-urethral			•			· •• •					
Frans-esoph. (non-Card.)	· · · · · · · · · · · · · · · · ·		and the constraint was to		aliana e acentra como con escapa de	,	CT-PT-SE-PH-PH-PT-PT-PT-PT-PT-PT-PT-PT-PT-PT-PT-PT-PT-			P	
Musculo-skeletal	7										
(Conventional)		_									İ .
Musculo-skeletal (Superficial)			<u> </u>								
Intravascular	-			-				-			
Other (Specify)											
Cardiac Adult	: .										
Cardiac Pediatric			: .							. ,	F1 1 2 2 24
Intravascular (Cardiac)						:					ŧ
Frans-esoph. (Cardiac)								•			:
ntra-cardiac							.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				1.
Other (Specify)						!					1
Peripheral vessel		•	•		,		,				-
			:							ż	ŧ
	}				•		•			-	:

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K082119

Note	1	Small	organ	includes	thyroid.	breast	and	testicle.

Note 2 Combined mode includes B/M; B/PWD: BDF/PWD: BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

Division of Reproductive, Abdominal and

Radiological Devices

Transducer: PVT-382MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Specific (Tracks 3)	В	M	PWD CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
phthalmic			ing in the same			· · · · · · · · · · · · · · · · · · ·			i	()	i
Fetal	P	P	P	Р	2 ;	Р	P	Ρ.	. P	P	5,7
Abdominal	P	P	P	P	2	Р	P	Р	P	Р	5,7
Intra-operative (Abdominal) Intra-operative (Neuro)									i	Î`	:
Laparoscopic Pediatric	, . P	P	. P	 P	2	P	P	P	P	P	5,7
Small Organ (Specify) (1)				er eest - e 1%		· · • • • • • • • • • • • • • • • • • •	1	1017017007000	-	;	an an ingresion and an arrange and a second
Neonatal Cephalic			•				· -	: • - • •			
Adult Cephalic		••	* I	•	•		;			,	;
Frans-rectal					ا ا		-	,		}	
Trans-vaginal				• •						. • •	-, · · · · ·
Trans-urethral	• • ···· ·										
Trans-esoph. (non-Card.)									. 4 m		A. A. I - 40 M
Musculo-skeletai	i						1				7
(Conventional)							1				
Musculo-skeletal (Superficial)	7.						1	•		i I	
Intravascular Other (Specify)			,				·			¥77	
Cardiac Adult			*,· - · ·					, *·····			
Cardiac Pediatric				-			/ *	;		:	
Intravascular (Cardiac)			- 1					langere e e			
Trans-esoph. (Cardiac)	1.							:			
Intra-cardiac	: '			• · · · • • ·							
Other (Specify)				·				<u> </u>		•	
Peripheral vessel		• •							;	,	
-							4				1

N = new indication: P =	previously cleared by	/ FDA; E =	added under	this appendix
Previous 510(k) of the tr	aneducar: KAR2110			

. ,				
Note	1 Small organ	includes	thyroid, bre	ast and testicle.

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division/Sigff-Off)

Division of Reproductive, Abdominal and

Radiological Devices

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Transducer: PVT-575MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	;Mod	e of (Operation								
Specific (Tracks 3)	В	М	PWD CWD		Combined (Specify)	ТНІ	Dynamic, Flow	Power	CHI 2D	3D	Other [Note]
)phthalmic		!									
Fet al	P	P	P	Р	2	Р	P	P	P	Р	5,7,8
Abdominal		,	· · · · · · · · · · · · · · · · · · ·		;		1				: •
Intra-operative (Abdominal)		i .			1		:		1		
Intra-operative (Neuro)											
Laparoscopic Pediatric	•				1			· · · · · · · · · · · · · · · · · · ·			1
Company of the special part of the second section (1997) and the second	4	<u>.</u>	د معاملات المحاسب		ا به موالاستان المساعلية				L		<u> </u>
Small Organ (Specify) (1)		· · ·	5 				· · · · · · · · · · · · · · · · · · ·		† †		
Neonatal Cephalic									, T		
Adult Cephalic	· · · · · · · · · · · · · · · · · · ·				· 			; processor (ļ		:
		•	1				· · · · · · · · · · · · · · · · · · ·		} · ·	ļ	
Trans-vaginal		<u>.</u>		,		,			·		
Trans-urethral				, .			-;	y	:	1	·
Trans-esoph. (non-Card.)		<u>.</u>			أسوال المائد		 	· • 	:		
Musculo-skeletal		,	- 2				i	!	1		;
(Conventional)			· · · · · · · · · · · · · · · · · · ·				·	! 	<u>!</u>		.,
Musculo-skeletal (Superficial)					,			<u> </u>	·	<u></u>
Intravascular							· .				ar artabona are cer
Other (Specify)					<u>.</u>						
Cardiac Adult					: 			٠ .	<u>.</u>		
Cardiac Pediatric						•					
Intravascular (Cardiac)			: 		:					i	1
Trans-esoph. (Cardiac)						: 1 			<u> </u>	· ·	
Intra-cardiac									:	!	
Other (Specify)						i L			1		,
Peripheral vessel	Ç W	:					:				,
			!				;				
 	=	··									
Other (Specify)								•			

N = new	indication; $P = previously cleared by FDA$; $E = added under it$	this appendix
Previous	510(k) of the transducer: K082119	

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Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

System: Aplio XG v4.0 SSA-790A
Transducer: PVT-674BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (O per ati	on								
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic		· · -	Į	÷				÷			<u></u>	1
Fetal	P	P	į P	, }	P	2	Р	P	P	P	:	, 5
Abdominal	; P	Р	P		Ρ	2	Р	. P	Р	· P		, 5
Intra-operative (Abdominal)								1				}
Intra-operative (Neuro)	alaban malam		3 contrate 44 11	- 184 Aug C - 1944 -	} *	into deservation et a - succe	luser Proba-				ir (ne ir negative begin i	;
Laparoscopic		:		. "							:	
Pediatric	, P	· F	. P		P	2	P	P	P	P		5
Small Organ (Specify) (1)			1			1		1		** -	,)
Neonatal Cephalic		-	İ		:							:
Adult Cephalic	. Territoria					:		:	!	,		
Trans-rectal	7	:	:	Acres and a sea of	Michigan Ch. Milania				;			
Trans-vaginal	į		t .	1		•		1		;		
Trans-urethral	1				and the same of th	-	**************************************			,/		·/·····
Trans-esoph. (non-Card.)		:	• • •			•	•	~{· · · · · ·			· · - · ·	<u>i</u> .
Musculo-skeletal		:			.,	· ·		:			, ,	:
(Conventional)									!		·	
Musculo-skeletal (Superficial)												
Intravascular	*********		<	,				· an ann man		regulare the second	ng dad Indahetifa	i net tiples and a
Other (Specify)									:			
Cardiac Adult		į.							!		• • • • • • •	
Cardiac Pediatric			;			" , -	:		<u> </u>			1
Intravascular (Cardiac)	Ť		,		:		-	!	T		•	•
Trans-esoph. (Cardiac)		1	i		1						1	
Intra-cardiac				1						.,	i	
Other (Specify)					.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		1					
Peripheral vessel				7			-	:				Ţ <u></u>
· }	:											t
		,										
Other (Specify)	:	:	7 						i			

N = new indication; P = previously cleared by FDA: E = added under this appendix Previous 510(k) of the transducer: K082119

Note I	Small	organ	includes	thyroid.	breast	and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD: BDF/PWD; BDF/MDF: BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

091295

Prescription Use Only (Per 21 CRF801.109)

Toshiba America Medical Systems, inc.

Aplio XG v4.0 SSA-790A

Transducer: PVT-661VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	, O! (Operation								
В	M	PWD CWD	Color Doppler	Combined (Specify)	THI	Dynamic;	Power	CHI 2D	3D	Other
<u>:</u>		t		· 	10 T W 10 10 10 10 10 10 10 10 10 10 10 10 10	,f :	***************************************			÷
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		als exemple commercial	;, •	·						
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	***			}						
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i P	P	p	P	2		T P	P	P		4,5
p"	_ P	P	p	2	P	P	Р	P	f	4.5
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Note 1 Small organ includes thyroid, breast and testicle. Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BI	
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BI	OF/MDF: BDF/MDF/PWD: 2D/CWD; BDF/CWD
Note 4 TDI	(Division Sign-Off) Division of Reproductive Abdominal and
Note 5 ApliPure	Amar land of
Note 6 MicroPure	MANWIN WYZ
Note 7 Precision Imaging (New)	(Division Stan-Off)
Note 8 STIC	(Division eight en)
Hole 7 3D color (New)	Division of Reproductive, Abdominal and
Note 10 STIC Color (New)	Radiological Devices 510(k) Number
Prescription Use Only (Per 21 CRF801.109)	510(k) Number

B·12

System: <u>Aplio XG v4.0 SSA-790A</u>
Transducer: <u>PVT-681MV</u>

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod		Operation	T							
Specific	В	M	PWD CWD	Color	Combined	THI		Power		3D	Other
(Tracks 3)			,	Doppler	(Specify)	-	Flow	İ	. 2D	,	Note
Ophthalmic	• •						<u> </u>			! :	!
(Fetal										i •	
Abdominal			·				·		· · · · · · · · · · · · · · · · · · ·	·	(· ·
Intra-operative (Abdominal)		, 			et see to the second second						
Intra-operative (Neuro)		· · · · ·						Ner*	consequences you	Territorius (n. 1911)	
Laparoscopic			i de la compania del compania del compania de la compania del compania de la compania del compania de la compania de la compania de la compania de la compania del compania							! !	}
Pediatric									·	i 	
Small Organ (Specify) (1)	. · ·				* - * m						·
Neonatal Cephalic	:				. =			•			
Adult Cephalic	····		a comment in the second second				-		;		<u> </u>
Trans-rectal	, P	P	P	P	2	P	p .			P	457
Trans-vaginal	P	:. Р	P	· : P	. <u></u> . 2	ı P	, <u>-</u> ,	<u>.</u>	. P	P	4,5,7 4,5,7
Trans-urethral	en gangan a .		article Committee and a		···-			E	. 1		1,0,1
Trans-esoph. (non-Card.)	÷.		recent to the second						i		
Musculo-skeletal		•									
Conventional)					:						
Musculo-skeletal (Superficial)			•		• • • • • •			C-144 W. B 1466	(m		
ntravascular							· · · · · · · · · · · · · · · · · · ·			.	
Other (Specify)			er to the formal etc.					-February 100			
Cardiac Adult			4		:						
Cardiac Pediatric					;	· ~					
ntravascular (Cardiac)						•			'	·	
Frans-esoph. (Cardiac)										- · · · · ·	
ntra-cardiae							ender of the second			, pr >	(m. 1.4.2.). (
Other (Specify)			A		:		:		- Marie - 74 - 2 - 4		
Peripheral vessel			,,					** *****			
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No. 10 10 10 10											:
Other (Specify)			en en en en en en en en en en en en en e		tan men an an						
= new indication; P = previously revious 510(k) of the transducer: I ote 1 Small organ includes thyroidely 2 Combined mode includes P.	K 082 d. b re	119 ast a	nd testicle.				_				
ote 2 Combined mode includes Boote 3 Combined mode includes Boote 4 TDI	/M; E /M; E	3/PW 3/PW	D; BDF/PWD;	BDF/MI	DF: BDF/MD. DF: BDF/MD. A	F/PW F/PW	D D; 2D/CWI	D; BDF/C	WD		
ote 5 ApliPure					//	1	"han	1			
ote 6 MicroPure					_//////	W_	MICH	Inn	<u>~</u>		_
ote 7 Precision Imaging (New)				(Divis	sion Sign-C)ff)		7			-
ote 8 STIC											
ote 8 STIC ote 9 3D color (New)				Divisi	on of Renr	oduo	ctive Ahr	iominal	and		
· · - · · - · -				Divisi Badin	ion of Repr ological De	oduc	ctive, Abo	dominal	and		

System: <u>Aplio XG v4.0 SSA-790A</u>
Transducer: <u>PVT-745BTV</u>

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	boM	e of	of Operation									
Specific (Tracks 3)	В	M	'PWD CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]	
Ophthalmic	•		1 ·							} 		
Fetal		. `							7 - 7 - 7 - 7		,	
Abdominal	P	·¬́P	P	Р	2	P	Р	P			5	
Intra-operative (Abdominal)	P	P	P	P	2	P	P	P			5	
Intra-operative (Neuro)	(terre and the event at the control					1, -188 H7 ala 74 P7 P F 4 a	·			
Laparoscopic		• • •										
Pediatric	Р	P	P	Р	2	P	Р	P			5	
Small Organ (Specify) (1)	P	. Р	P	Р	2	Р	, Р	Р	Ţ		5	
Neonatal Cephalic		•			!		:					
Adult Cephalic			*								i.	
Trans-rectal								45-6	·		i	
Trans-vaginal								•	: "" '	ŗ · · · ·	!	
Trans-urethral		· · ·						(market military medical) reserve			!	
Trans-esoph. (non-Card.)	•	•	•		• •			(. ,			
Musculo-skeletal		:			1					İ		
(Conventional)							· · · · · · · · · · · · · · · · · · ·	1		<u>.</u>	<u> </u>	
Musculo-skeletal (Superficial)	,		**							1	1	
Intravascular					siare is a communication						i 	
Other (Specify)												
Cardiac Adult				i						1		
Cardiac Pediatric								•			:	
Intravascular (Cardiac)					•	•		•	-		:	
Trans-esoph. (Cardiac)	•	•		: :			1	1		· ·	;	
Intra-cardiac				:		•	1					
Other (Specify)				 					,	7		
Peripheral vessel							a tagente in an in a)		
				r r						1		
the same of photographic and a single section of the same are some										· •		
Other (Specify)								,			ē	

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle. Note 2 Combined mode includes B/M; B/PWD; BDF/PWD Note 3 Combined mode includes B/M; B/PWD; BDF/PWD Note 4 TDI Note 5 ApliPure	BDF/MDF: BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 6 MicroPure Note 7 Precision Imaging (New) Note 8 STIC Note 9 3D color (New) Note 10 STIC Color (New)	(Division Sign-Off) Division of Reproductive, Abdominal and Radiological Devices 510(k) Number
Prescription Use Only (Per 21 CRF801.109)	orolly number

System: Aplio XG v4.0 SSA-790A
Transducer: PVT-770RT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Operati	00						,		· · · · · · · · · · · · · · · · · · ·
Specific (Tracks 3)	В	M	PWD	CWD		Combined (Specify)		Dynamic Flow	Power	CHI 2D	3D	Other [Note
phthalmic			÷			L					; ; : ;	:
etal				:		1		1			:]
bdominal						:						
ntra-operative (Abdominal)		:		:							!	
ntra-operative (Neuro)	***************************************											:
aparoscopic			.'	7				1		,		
ediatric		!			,	1	,		11 - A - 10 - 10 - 10 - 10 - 10 - 10 - 1			
Small Organ (Specify) (1)		:					,. <u>-</u>				٠	
leonatal Cephalic				-		:		: -}	· 	;	4 yar. 4	3 9 = - 1 = -
Adult Cephalic						(·,·		·
rans-rectal	P	P	. P		P	. 2	P	P	P			5
rans-vaginal		·				A september of the second	· •	į (
rans-urethral	1	2				·						
Frans-esoph. (non-Card.)						1			humanist of Page			
Musculo-skeletal Conventional)		; !	k.		•	•	j	•				; r
Musculo-skeletal (Superficial) ntravascular		;						*	ļ • •- ·-	;	;- · · · ·	
Other (Specify)	4 11.141 21				****	art t da, sant Statitoric int		.,	[
Cardiac Adult		,								:		
Cardiac Pediatric						,		1				_, ,
ntravascular (Cardiac)		:	· ·	-	: •			. -		:		
Frans-esoph. (Cardiac)											i i	
ntra-cardiac		1.	:							1	1	a China e a mare
Other (Specify)	,	 		:			1					
Peripheral vessel									!	1		
		•				•	ì.			•	•	
NAMES AND ADMINISTRAÇÃO CONTRACTOR DE MODERNOS CONTRACTOR DE LA SECULIA					***							
Other (Specify)						-		i				

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K082119

Note	1 Cmall	Argan	includes	thoroid	breast and	testicle
Note	i Small	organ	includes	invroia.	preast and	testicie.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD: BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

391295

Prescription Use Only (Per 21 CRF801.109)

Transducer: PLT-604AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on								
Specific (Tracks 3)	B	! M	PWD	CWD		Combined (Specify)		Dynamic Flow	Power	CHI 2D	3D	Other [Note]
phthalmic	}	:	1		i			<u> </u>		5 T	1	1
Fetal		; ·										
Abdominal					-	;				: '		• '
ntra-operative (Abdominal)					7	1					*	
ntra-operative (Neuro)												
aparoscopic	1				:		-		-	·1 ·		
Pediatric	;	71	. ,			· · · · · · · · · · · · · · · · · · ·						
Small Organ (Specify) (1)	, P	P	: P		P	2	Р	P	P	*P	Í	5
Veonatal Cephalic			· · · · · · · · · · · · · · · · · · ·		·					· -		
Adult Cephalic	4			÷	1		•	1.		"		
rans-rectal					,, 	i						
rans-vaginal		• •				:					: ***	
rans-urethral						<u></u>		·		:	ř ·	
Frans-esoph. (non-Card.)		in 21.	- -			ajama – paga a sasa						7 / do 11-4
Musculo-skeletal	P	ï P	. Р		Р.	2	Þ	p	. р	р.		 S
Conventional)		; '			P	∠ تانیا	r	r	r	r	<u> </u>	
Musculo-skelctal (Superficial)	1 P	P	, P		P	. 2	Р	P	Р	P		. 5
ntravascular				,,,,,,								
Other (Specify)												
Pardiac Adult										-		
Cardiac Pediatric					1		,,			•		
ntravascular (Cardiac)						, ,		**** **** ***				
Ггалs-esoph. (Cardiac)		. 10.022										
ntra-cardiae			1	**********						.,,,,,,,		1
Other (Specify)		7		.,				., 				1
Peripheral vessel			-,		!	1 plant - render		:				7. ~
	P	: P	; P		Р	. 2	P	P	P	P		1 5
common a servicio con construir e servicio de la 1 programa desagna desagna (1) a servicio (2) de 10 a gallo (1) gi di	E Francis (Car)				ware			and the state of the state of the				!
Other (Specify)		_			•				•			

Note 1	Small	organ	includes	thyroid,	breast	and t	testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF: BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

Toshiba America Medical Systems, Inc.

Aplio XG v4.0 SSA-790A

Transducer: PLT-704AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Operation			4- (V top	المقاص بيورون راجع اجاروكي	والمراجعة المراجعة		··· andhine	anangat was sampunda sa
Specific (Tracks 3)	В	М	PWD CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other Note
Ophthalmic							1			Problem array	
Fetal			•								!
Abdominal		•					!		1		:
Intra-operative (Abdominal)									•	, m m. z	
Intra-operative (Neuro)		··			•	-	·,				
Laparoscopic											1
Pediatric						•	· · · · · · · · · · · · · · · · · · ·				
Small Organ (Specify) (1)	P	. P	P	P	2	Р	. P	Р	P		; 5
Neonatal Cephalic						• •	-,		•' •		
Adult Cephalic	• •	•		•	f.						
Trans-rectal							i			**	:
Trans-vaginal			:	-							
Trans-urethral											igina ana
Trans-esoph. (non-Card.)	*****	1									.,
Musculo-skeletal	р	יי	ם י	р	2	р.	p	р.	P		5
(Conventional)											, , ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Musculo-skeletal (Superficial) Intravascular	P	<u>P</u>	Р	Р.	2	. P	<u>P</u>	P	P		5
Other (Specify)								•			
Cardiac Adult	·: -	 :									
Cardiac Pediatric		•	• •				~		ال. حمد ال		
Intravascular (Cardiac)					<u> </u>		* * * * *				
Trans-esoph. (Cardiac)		:			*** * * * *				:		
Intra-cardiac		•	· · · · · · · · · · · · · · · · · · ·		7	-,		/			-, -
Other (Specify)		: .		·- · · · · · · · · · · · · · · · · · ·		·			÷	···-	
Peripheral vessel								;	21 11 4 4 15 4		7
(· Р	Р	Р ;	: P	2	P	, ъ	: Р	· P		5
	•		•	•			•		•		,

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K082119

Note 1	l	Small	organ	includes	thyroid,	breast	and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD, Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD, BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

Prescription Use Only (Per 21 CRF801.109)

. Toshiba America Medical Systems, Inc.

Aplio XG v4.0 SSA-790A System: Transducer: PLT-704SBT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Specific	В	M	PWD	CWD	Color	Combined	THE	Dynamic	Power	CHI	3D	Other
(Tracks 3)					Doppler	(Specify)		Flow		2D	1	[Note]
phthalmic				i				}			, , , , , , , , , , , , , , , , , , ,	
Fetal	i				1	•		!		,		L
Abdominal	•			· · · · · ·		*		!			i i	
Intra-operative (Abdominal)			J							,		
Intra-operative (Neuro)		24 1				1						1 7 2 10-
Laparoscopic			-		• •	:						i i
Pediatric				1								
Small Organ (Specify) (1)	P	P	Р	· ·	Р	2	Р	P	Р	P		5
Neonatal Cephalic		•		,, , , ,		7	1				• 	: :
Adult Cephalic	•	. ,	;	· -	. 2.12 201.0 20		:		,			
Trans-rectal						·	·	i		1 .1	,	
Trans-vaginal			:				i January same		ì	i ione as		i Language
Trans-urethral							ţ) ,			
Trans-esoph. (non-Card.)						1			l ()	<u>.</u>		:
Musculo-skeletal	P	P	· p	•	P	÷ 2	! Р	Р	Р	P		5
(Conventional)						i	·	÷	i i			
Musculo-skeletal (Superficial)	.P	Ρ.	Ρ.		P	2 .	Р	P	' Р	P		
Intravascular											· · - · · ·	
Other (Specify)												
Cardiac Adult								· 				
Cardiac Pediatric	:		-	2		· · · · · · · · · · · · · · · · · · ·					• • •	
Intravascular (Cardiae)			-				· ···- ·			-		
Trans-esoph. (Cardiac)		<u> </u>				<u> </u>		.i	· 			
Intra-cardiac	****	, .		.,				.;				: ************************************
Other (Specify)					· ·	A separate on the second					· · · · · · ·	
Peripheral vessel		_	_					;	,		,	ا
	Р	; P	P	•	. P	2	P	, P	. Р	P		; 5

N = new indication; P = previously cleared by FDA; E = added under this appendixPrevious 510(k) of the transducer: K082119

Mate	i Small	organ	includes	thsmoid	breast	and	testicle
Note	r Small	organ	menuaes	invraia.	preasi	апо	testicie.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD: BDF/PWD; BDF/MDF: BDF/MDF/PWD; 2D/CWD: BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

Division of Reproductive, Abdominal and

Radiological Devices

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-705BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Operation		earrenne e		<u>,</u>			2	
Specific (Tracks 3)	В	M	PWD CWD	Color Doppler	Combined: (Specify)	THI	Dynamic Flow	Power	2D	30	Other [Note]
phthalmic			i			•••					
Fetal			***								
Abdominal	Р	Р	· P	; Р	2	ρ	Р	Р	Р	;	. 5
ntra-operative (Abdominal)	: P	P	P	P	2	P	P	P	P		5
ntra-operative (Neuro)			.1					 		• }	
Laparoscopic	•-· •• · -		•••				.1				
ediatric	"; P	P	P	P	2 ,	P	P	P	Р		: 5
Small Organ (Specify) (1)	P	P	P	. Р	2	Р	P	Р.	Р		5
Veonatal Cephalic		1		1			<u> </u>	: Lucia de la casa		(
Adult Cephalic				1	1) 	
rans-rectal						10 154 1	T				1
Trans-vaginal										; 	1
Frans-urethral	, · · ·	•								1	· ·
Frans-esoph. (non-Card.)					1				: 	<u>:</u>	<u>.i</u>
Musculo-skeletal								•	į	{	i
Conventional)							- -				.L
Musculo-skeletal (Superficial)										i i	:
ntravascular	.,			. googa to po bianylampia		***	, ,				
Other (Specify)	. :			general e la					÷	-	-5%
Cardiac Adult							many construction	:	2 Transless part to F		
Cardiac Pediatric		<u>.</u>					į –			1	
Intravascular (Cardiac)					•					į	
Frans-esoph. (Cardiac)		:							ا دام محمد شده		.1
ntra-cardiac		1					ļ			`	
Other (Specify)							·		.,		
Peripheral vessel							1		-	÷	
							*	-			

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K082119

Note 1	Small	organ	includes	thyroid,	breast and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF: BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sigh-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

System: Aplio XG v4.0 SSA-790A Transducer: PLT-705BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on								
Specific (Tracks 3)	В	М	PWD	CWD	Color Dopp i er	Combined (Specify)	тні	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic	J - ""	••• ····· ·		-		The State of States		!				
Fetal	:			τ			· · · · · · ·					•
Abdominal	. Р	Р	P		P	2	P	P	P	' P	- Trobe - seen a	5
Intra-operative (Abdominal)	P	Р	Р		P	2	Р	P	P	P		5
Intra-operative (Neuro)					* *** * ******							
Laparoscopic	7		•••			7		- hate chape w		······································	• • •	
Pediatric	P	P	P		P	2	P	Ъ.	P	P		5 .
Small Organ (Specify) (1)	Р	Р	Р		P	2	P	P	P	: "P		5
Neonatal Cephalic						· · · ·	-	•		:	· y	
Adult Cephalic								7			······································	
Trans-rectal						,		;				
Trans-vaginal	ه چه ده خد په									٠,		i i
Trans-urethral									., ., ., .,	! !		
Trans-esoph. (non-Card.)		,								i .		:
Musculo-skeletal (Conventional)			:	. '		:					•	:
Musculo-skeletal (Superficial)							*-					
Intravascular						-						
Other (Specify)						.,		7		•	•••••	
Cardiac Adult	• • •	-	• •••		***							•
Cardiac Pediatric	a. 1 %				·• · · · · ·							
Intravascular (Cardiac)					•	·						:
Trans-esoph. (Cardiac)			•	<i>-</i>		:						-
Intra-cardiac		•••••				<u> </u>		را بيد الياد سيناسد				
Other (Specify)						A		سند		·		···-
[Peripheral vessel	م · · ·							· į.		: 		
· ;				:								,
										:		
Other (Specify)								··· · · · · · · · · · · · · · · · · ·				

N = new indication; P = previously cleared by FDA: E = added under this appendix Previous 510(k) of the transducer: K082119

Note 1	Small	Organ	includes thyroid	heart and	tectiole
11000	Julgu	Organi	THEIRIGS HITH OIL	i. Dieasi and	resource

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

System: Aplio XG v4.0 SSA-790A Transducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			peration							,	,
Specific	, В	M	PWD CWD			THI		Power		3D	Other
(Tracks 3)				Doppler	(Specify)		Flow		2D		Note
phthalmic					·- ·				۰		}
Fetal		•	1							,,,, ,	
Abdominal		• •			J						
Intra-operative (Abdominal)		• •									
Intra-operative (Neuro)		•••								 !	
Laparoscopic		•							:		
Pediatric										i.	
Small Organ (Specify) (1)	Р	P	P	P	2	P	P	P	P	!	5.6,7
Neonatal Cephalic				• • •							·
Adult Cephalic										i	
Frans-rectal										1	
Frans-vaginal											
Frans-urethral						:					
Frans-esoph. (non-Card.)									.		
Musculo-skeletal	P	P	· P	Р	2	Р	P	P	; P		5,6.7
(Conventional)											
Musculo-skeletal (Superficial)	Ρ	Į,	P	Р	2	P	Ρ	P	į.	;	5,6.7
Intravascular							**** - : **** **** . : : : :		· · · · -	· ·	.;
Other (Specify)										,	
Cardiac Adult	٠.			•		,- ·					<u>i</u>
Cardiac Pediatric			•								;
intravascular (Cardiac)			· ·					•			· · ·
Frans-esoph. (Cardiac)	A										÷
intra-cardiac										ć	
Other (Specify)					1					· ·	-;
Peripheral vessel	6	r.	n	:		n	n	n		1	:
	Р	P	P	P	2	Р	. Р	P	P		5.6,7

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K082119

Note 1 Small organ includes thyroid, breast and testicle.	
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD: B	DF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; B	DF/MDF; BDF/MDF/PWD: 2D/CWD: BDF/CWD
Note 4 TDI	11 10 091
Note 5 ApliPure	hond In Wha
Note 6 MicroPure	(Division Sign-Off)
Note 7 Precision Imaging (New)	(Division Sign-On)

Note 8 STIC
Note 9 3D color (New)
Note 10 STIC Color (New)

Radiological Devices

510(k) Number

Prescription Use Only (Per 21 CRF801.109)

 System:
 Aplio XG v4.0 SSA-790A

 Transducer:
 PLT-1202S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Specific	В	M	PWD CWD		Combined	THI	Dynamic	Power	CHI	3D	Other
(Tracks 3)			-	Doppler	(Specify)		Flow		2D		[Note]
) Dphthalmic	•			ومن داد 1969 - سادانو	<u> </u>		All a lind				
Fetal		•									
Abdominal	, ,		7 = 1 1F June 1		1					,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Intra-operative (Abdominai)	P	P	P	Р	2 .	P	P	P			4,5
Intra-operative (Neuro)			1		1	25 1.00 5					····
Laparoscopic	•	••	• •			.					
Pediatric					i- · · · · · · · · · · · · · · · · · · ·						· · ·
Small Organ (Specify) (1)	· p	P	P	P	2	P	P	Р			4,5
Neonatal Cephalic					i	**	f***				
Adult Cephalic				* 100000 10 10 10 10000	· · · · · · · · · · · · · · · · · · ·		1		** ***	 !	
Trans-rectal			distributing some was	The Control of Control	glaven verste. De et nav en enne de e	****	eriant new er en a fin er aan en en.		et a same e de a ramá		
Trans-vaginal			•	* *** *	i		11-1		-		 !
Trans-urethral					Ţ. 		<u> </u>		Decrees.	• • • • • • • • • • • • • • • • • • •	
Trans-esoph. (non-Card.)	•						· · · · · · · · · · · · · · · · · · ·	-			. "
Musculo-skeletal (Conventional)	Р	: P	Р	Р	. 2	Р	P	þ	4	; - i	4,5
Musculo-skeletal (Superficial)	···	P	P	P	. 2	P	P				4,5
Intravascular				· ·		-	1	•			
Other (Specify)	•	•		****** *** ** *** ***	·····		ifica en araban. T		·		
Cardiac Adult					•						•
Cardiac Pediatric					:	- •••••			57 1 *** 7	• • •	
Intravascular (Cardiac)		• •							· ·	· · · · · · · · · · · · · · · · · · ·	2
Trans-esoph. (Cardiac)	•				7		1				
Intra-cardiac						******	man e somerende end			, els s.s.,eee.	`
Other (Specify)	,		The second secon		· · · · · · · · · · · · · · · · · · ·						· · · · · · · · · · · · · · · · · · ·
Peripheral vessel					······································	de al alberra					
	Р	p	. P	Р	2	Р	· P	Р			4.5
			ŧ		: '						

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle. Note 2 Combined mode includes B/M; B/PWD; BDF/PWD	: BDF/MDF: BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD	
Note 4 TDI	
Note 5 ApliPure	11
Note 6 MicroPure	- IAMA IN WOLD
Note 7 Precision Imaging (New)	(Division Sign-Off)
Note 8 STIC	
Note 9 3D color (New)	Division of Reproductive, Abdominal and
Note 10 STIC Color (New)	Radiological Devices /
Prescription Use Only (Per 21 CRF801.109)	510(k) Number <u>5091295</u>

System: Aplio XG v4.0 SSA-790A Transducer: PLT-1204AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Operation									
Specific (Tracks 3)	. В	M	PWD CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]	
Ophthalmic	•	1.			<u> </u>				-		i	
Fetal	* ·			1					Ť			
Abdominal		-,					.,				1	
Intra-operative (Abdominal)				,					:			
Intra-operative (Neuro)				p 27 - 20-20-1-1-1	Approved and the finance of				i	,	F-100-101-1	
Laparoscopic	,			;	,				•	Γ		
Pediatric	1			:	**							
Small Organ (Specify) (1)	p	P	Р	P	2	Р	, P	P	:		4.5.6	
Neonatal Cephalic		• • • •		· · · ·	:		(#1455 (#25)) () 				r	
Adult Cephalic		-			:					î .		
Trans-rectal						*****						
Trans-vaginal	, .									1		
Trans-urethral	:					·	1	,	[!	;	
Trans-esoph. (non-Card.)	.,				-	1	Ţ · · ·			:	1	
Musculo-skeletal	. P	P	, P	Р	2	P	P	. Р		:	4,5,6	
(Conventional)							<u> </u>			: 		
Musculo-skeletal (Superficial)	P	. P	Р.	. Р	.2	P	: Р	Р.	÷		4.5.6	
Intravascular	. <u></u> .					r 			· · · · · · · · ·			
Other (Specify)			-w·						i ±	·		
Cardiac Adult	- :	÷				y · ·		,		·		
Cardiac Pediatric					1	÷					ļ	
Intravascular (Cardiac)							, , , , , , , , , , , , , , , , , , , ,					
Trans-esoph. (Cardiac)				<u>:</u>			.d					
Intra-cardiac	:		4		.h	Tababannang	Santana a a a a a a a a a a a a a a a a a					
Other (Specify)	<u>.</u>				ingerta in material kalendari			y- 		·		
Peripheral vessel	P	: : р	P	; P	2	;	}		ı			
	. 12	. I	r	۲	2	P	P	P			4,5,6	
Other (Specify)	-, -				·		·					
Short poenty							wes				:	

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.	
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;	BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;	BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TD1	
Note 5 ApliPure	1 and pho Who
Note 6 MicroPure	
Note 7 Precision Imaging (New)	(Division Sign-Off)
Note 8 STIC	Division of Reproductive, Abdominal and
Note 9 3D color (New)	·
Note 10 STIC Color (New)	Radiological Devices,
	510(k) Number 2091295
Prescription Use Only (Per 21 CRF801.109)	STU(K) NUMBER TYO YES LO

Toshiba America Medical Systems, Inc.

System: Aplio XG v4.0 SSA-790A

Transducer: PLT-1204BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Ope	ration								
Specific (Tracks 3)	В	М	PV	VD CWD		Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic				en an service cy		a nagrapaga paga a nagrapaga a T	plate in large de	1	PF F 1 1 1 1 1 1 1 1 1			
Fetal	•	: -			- • • •	4				2		
Abdominal										1	,	
Intra-operative (Abdominal)		: -	-				 		, · · · · · · · · · · · · · · · · · · ·	:		
Intra-operative (Neuro)						'					,	
Laparoscopic		; -		· · · · · · · · · · · · · · · · · · ·	· ·-			*****				
Pediatric							**					
Small Organ (Specify) (1)	·P	Р		P !	P	2	P	P :	P			4,5.6
Neonatal Cephalic			-÷		=	i			,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,,			1 **** ****
Adult Cephalic	• •									., w .		
Trans-rectal		•	***	15	* •	*** **					= :	
Trans-vaginal		:		:		:		i	: "	i		
Trans-urethral										1		
Trans-esoph. (non-Card.)		••	:	1			:	eripensiarranara assess		···		
Musculo-skeletal	ο		• • • •	P .	p	2	, P	p.	р	•		4.5.6
(Conventional)		. r		r 		. 2		i	ı			4.3.0
Musculo-skeletal (Superficial)	. P	P		P :	P	: 2	Р	Р	Р	:		4,5,6
Intravascular	_									:		
Other (Specify)							 *					
Cardiae Adult								1				
Cardiac Pediatric				, ,,,,,		1						i
Intravascular (Cardiac)								:				
Trans-esoph. (Cardiac)				1						-:	,	
Intra-cardiac		•						engan en en en en en en en en en en en en en		: "		
Other (Specify)	1 4**	;							i		•• •• ••	
Peripheral vessel				1	• • • •			·			••	
	P	P	:	P	Р	. 2	P	. P	, P	•		4,5,6
rido ambrolos de deles ridados sen santi de la coleta deles de las		<u>.</u>										
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K082119

Note I	Small	organ	includes	theroid	breast	and testici	p
TABLE I	cittian	or Ean	HICHUGCS	mynnu.	ти саль	and restruct	٠.

Note 2 Combined mode includes B/M: B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD: BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TD

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-1204AX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human, body as follows:

Specific (Tracks 3)	i	В .	М	PW	D:	CWD,			ombined Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
phthalmic		:	••		3	1			* · **** · · · · · · · · · · · · · · ·	• • • • • •			:		·
Fetal			•	•							:		. "		
Abdominal											1]
ntra-operative (Abdominal)		· ·									1		.,		
ntra-operative (Neuro)										,					
aparoscopic	•	• :	•					•		•	i				
Pediatric	•	•			;	•	•								
Small Organ (Specify) (1)		P	Р	P			P	•	2	ñ	P	P			4,5.6
Veonatal Cephalic		- 7			,						7				
Adult Cephalic					.,						1				
Frans-rectal											i				
Frans-vaginal								:			· .i		. ;		
Trans-urethral												i			
Frans-esoph. (non-Card.)							:			:					
Musculo-skeletal		Р.	Р	P	ı Î		P		2	Р	Р	Р	!	!	4,5,6
(Conventional)													.:)
Musculo-skeletal (Superficial)		Ρ,	Р	P			P		2	Р	P	P .			4.5,6
ntravascular										.,					
Other (Specify)	- .									·					<u>.</u>
Cardiac Adult												···		٠.	
Cardiac Pediatric		. :		2											
ntravascular (Cardiac)			•				•			· •	****			• •	
Frans-esoph. (Cardiac)						-						<u>.</u>	-4		
ntra-cardiac				Y				. ;	Assau as Transacta	-2	والمراسطان			<u></u>	
Other (Specify)														tana i a	
Peripheral vessel				_			D	:		į "	1	D			
		P	P	F	,	:	P		2	P	Р.	P			4,5,6

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K082119

N. F.		C 11			1		
Note	ı	Small organ	includes	thyroid.	preast	and	testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(División Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices,

510(k) Number

oer ____

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-1204BX

}

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Specific (Tracks 3)	В.	M	;PWB	CWD	Color Doppler	Comb (Spec	ined- cify)	THI	Dynamic Flow	Power	2D	3D	Other [Note]
hthalmic						·						,	
etal						("-			, i.e		1	i	F
bdominal		***	•		f	angaran mer	** *** **	,					
tra-operative (Abdominal)	• • •		•	:							:		
tra-operative (Neuro)						[1 -				1		:
aparoscopic				£		30	-	** ***				:	
ediatric									1		:		
mall Organ (Specify) (1)	P	p	þ	•	P P	! 2	- - -	Р	; P	Р		,	4.5,6.7
eonatal Cephalic		`	•			•		•					
dult Cephalic				•					1		!		· ····
rans-rectal	,		•		· · · ·					n = .=	1	,	
rans-vaginal							,		7			`i	•
rans-urethral									1	.,	·		- ,
rans-esoph. (non-Card.)								•					7
lusculo-skeletal	p.	P	n		. Р		· 1	p	P	р			4,5,6,7
Conventional)	1-		b		r				, , , , , , , , , , , , , , , , , , ,				
fusculo-skeletal (Superficial)	P	P	P		P		2	P	P	Р.	1		4,5,6,
ntravascular													
ther (Specify)			-										
ardiac Adult												<u> </u>	
'ardiac Pediatric											:		
itravascular (Cardiac)								~	<u>. i</u>				
rans-esoph (Cardiac)													
ntra-cardiac													. Journey was
Other (Specify)						1							1
eripheral vessel						- •			1				
	P	P	Ъ		P		2	P	Р	Р	:	i	4,5,6,
			_					_				i į	

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K082119

Note I Sm	all organ	includes	thyroid.	breast	and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD: BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices,

510(k) Number ___

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-1204MV

1

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode				300 300 3	20124	D	n	CIL	3 D	Other
Specific (Tracks 3)	; B '	M	PWD.CWD		(Specify)	1 Mi	Dynamic Flow	rower	2D	30	[Note]
plithalmic						,,,				 	; :
Fetal	1 1	• • •			1						(
Abdominal	7			;						! : 	
ntra-operative (Abdominal)		,									·
ntra-operative (Neuro)						_			1	ì	
aparoscopic	•••			, <u></u> , , ,		-				: :	
Pediatric		•			1,						:
Small Organ (Specify) (1)	Р	Р	Р	Р	2	P	P	P		Р	5,7,9
Veonatal Cephalic				:							: :
Adult Cephalic				;					!		
Frans-rectal				-					1		:
Frans-vaginal		•		:	•						
Trans-urethral					:				:		1
Trans-esoph. (non-Card.)							ا د مدد و سوری				: :
Musculo-skeletal (Conventional)	P	Р	Р	. P	2	P	P	P	į	Р	5,7,9
Musculo-skeletal (Superficial)	P	P	P	P	2	Р	P	P		Р	5,7,9
Intravascular			• •	•	1						
Other (Specify)					1					,	
Cardiac Adult	• •			.						1	
Cardiac Pediatric									. `		
Intravascular (Cardiac)		•		;							
Trans-esoph. (Cardiac)	٠	1			1	,,	, ,			1	
Intra-cardiac					:					•	
Other (Specify)	,		,		1						
Peripheral vessel				;	-,					•	
	Р	þ	P	. Р	: 2	p	, P	Р	•	P	5,7,9
Other (Specify)	. :										

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.	
Note 2 Combined mode includes B/M; B/PWD: BDF/PWI	D: BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M: B/PWD: BDF/PWI	D: BDF/MDF; BDF/MDF/PWD; 2D/CWD: BDF/CWD
Note 4 TD1	1 1 1 1
Note 5 ApliPure	Marin Na
Note 6 MicroPure	(Division Sign-Off)
Note 7 Precision Imaging (New)	· · · · · · · · · · · · · · · · · · ·
Note 8 STIC	Division of Reproductive, Abdominal and
Note 9 3D color (New)	Padiological Devices
Note 10 STIC Color (New)	Radiological Devices
	510(k) Number
Prescription Use Only (Per 21 CRF801.109)	

System: Aplio XG v4.0 SSA-790A
Transducer: PET-510MB

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod		Operati			,						
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
phthalmic		<u>.</u>	 !			1					gart graye ya	<u></u>
Fetal				7' " '								
Abdominal		· • • • • • • • • • • • • • • • • • • •				,		1				
Intra-operative (Abdominal)	* 1-,	; •••··		- · · · · · · · · · · · · · · · · · · ·		:		1		*		
Intra-operative (Neuro)	,			A	:							
aparoscopic	· · ·			•	: :			† · · ·	•	:		
Pediatric				į		:	•	!				
Small Organ (Specify) (1)			•	4				ayanga nguri sa sa sa sa sa sa sa sa sa sa sa sa sa	. =	~ · · ••·	•	
Noonatal Cephalic			·		*****					-		:
Adult Cephalic		· · ·			* *			7 mm = 1 m = 1	1 24 -41 47			
Frans-rectal		T						<u> </u>	*** ****	in 14 pers 1 and		
Trans-vaginal				:		1						, '
Frans-urethral	enler a miner	`~~~.		4-n	je 14 · · · · · · · · · · · · · · · · · ·	}		·		, ,,.		; :
Frans-esoph. (non-Card.)		i		1				i				`
Musculo-skeletal]				A 14 1 1 1 1 1		
(Conventional)								: 				<u> </u>
Musculo-skeletal (Superficial)				!				4				
Intravascular										عادي بين دند .		
Other (Specify)												
Cardiac Adult			1	!		:						:
Cardiac Pediatric		:]			•			_
Intravascular (Cardiac)			•			î !		····			•	_
Trans-esoph. (Cardiac)	P	: P	P	P	Р	3	Р	***		1		4
ntra-cardiac									or starts. (
Other (Specify)												
Peripheral vessel		Ţ										
					•	1		•	!			•
galler of the other to the description of the contract of the		ė.			1			\$ 10.0001 0-12 001550-1	4 4111			
Other (Specify)		:	:			1				-		

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K082119

Note	Small	organ	includ	es ti	nyroid	, breast	and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TD1

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STI€

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

Aplio XG v4.0 SSA-790A System: Transducer: PC-20M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of Operation				iano de care				
Specific (Tracks 3)	В	M PWD CWD		Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
)phthalmic									·	
Fetal	:			:		:		•		
Abdominal	,					;				
Intra-operative (Abdominal)		1				1	,			
Intra-operative (Neuro)	7 7		,, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					:		
Laparoscopic			• •		•			:		
Pediatric						1				
Small Organ (Specify) (1)	3	in the second				1			:	
Neonatal Cephalic		r								
Adult Cephalic		· · · · · · · · · · · · · · · · · · ·				1	· · · · · · · · · · · · · · · · · · ·		:	
Trans-rectal						; 			i	
Frans-vaginal							!	:	i	
Trans-urethral	**************************************	m, a reservament darbitat en derde	H	4 to 1				- 6- 1-1	:	t
Trans-esoph. (non-Card.)			•	# 150 F 150 F 150		:				<i>.</i>
Musculo-skeletal				· · · · · · · · · · · · · · · · · · ·			(!
(Conventional)						=,,	, (:	
Musculo-skeletal (Superficial	1)									
Intravascular		, Tana ana yangga at a sa ta	11.00 1 \$ 6		i					
Other (Specify)						.i		!	1	
Cardiac Adult		Р				1				
Cardiac Pediatric		Р								
Intravascular (Cardiac)	i						:			
Trans-esoph. (Cardiac)		1								
Intra-cardiac	,		1			1	:			
Other (Specify)									1	
Peripheral vessel				- ,		1				1
	•					1	i	•		1
							:			
Other (Specify)		1					:			:

N = new indication; $P = previously cleared by FDA$; $E = added v$	under this appendix
Previous 510(k) of the transducer: K082119	

Mota i	I Small	Organ	includes	threaid	branct	and to	acticle

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD: BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD: BDF/CWD

Note 4 TDi

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New) Note 10 STIC Color (New)

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices,

System: Aplio XG v4.0	SSA-79 <u>0</u> A		·				·	
Transducer: PC-50M								
Intended Use: Diagnostic ultraso	and imaging or fluid flow	analysis	of the human body	as follows:				
Clinical Application	Mode of Operation		• • • • • • • • • • • • • • • • • • • •					.1
Specific (Tracks 3)	B M PWD CWD		Combined THI (Specify)	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic Fetal Abdominal					To a see brown			
Intra-operative (Abdominal)	راياء فستصفيه بالمقدية الأرايك الموسية الك	,_4,4-0 _4 ,		†		;		* *** 1
Intra-operative (Neuro) Laparoscopic	· · · · · · · · · · · · · · · · · · ·		in the second second					erate de la centaga.
Pediatric	The second secon		* * * * * * * * * * * * * * * * * * *	:				
Small Organ (Specify) (1)						T		
Neonatal Cephalic Adult Cephalic			: -:: -: -: -: -:	1		†		·
Trans-rectal	e encorrer e en el comunicación.					1		
Trans-vaginal	• • • • • • • • • • • • • • • • • • • •							·
Trans-urethral	The second secon		The same of the same same and the same of the same at	†		, the second		
Trans-esoph. (non-Card.)								!
Musculo-skeletal (Conventional)	;		,	1		; ;		į
'Musculo-skeletal (Superficial)	· · · · · · · · · · · · · · · · · · ·			<u>.</u>		<u> </u>	• • • •	
Intravascular			• •					
Other (Specify)						7		
Cardiac Adult		to a section	e e e e e e e e e e e e e e e e e e e					
Cardiac Pediatric	p			<u>.</u>		<u>.</u> 1		
Intravascular (Cardiac) (Trans-esoph. (Cardiac)						·		:
Intra-cardiac	render specially a second of the second of t			<u> </u>		<u>.</u>	, ,-	
Other (Specify)		15 (80) 1 1 4 4		i Çanınının sanını		:	,	
Peripheral vessel	1			1	j			!
	Р			1		:	:	
· Other (Specify)	And the second s		• · · · · · · · · · · · · · · · · · · ·		·			· -
N = new indication; P = previous Previous 510(k) of the transducer	sly cleared by FDA; E = ac r: K082119	dded unde	er this appendix	Anny medican in many d		· <u>-</u> .		• • • • • • • • • • • • • • • • • • • •
Note 1 Small organ includes thyr Note 2 Combined mode includes Note 3 Combined mode includes	B/M; B/PWD; BDF/PWI	D; BDF/M D: BDF/M	IDF; BDF/MDF/P\ IDF; BDF/MDF/P\	WD WD; 2D/CV	VD; BDF.	/CWD		
Note 4 TD1 Note 5 ApliPure			1	11	71			
Note 6 MicroPure			11 Ans	m	Nho	m		_
Note 7 Precision Imaging (New) Note 8 STIC		(Divi	sion &ign-Off)					-
Note 9 3D color (New)		Divis	ion of Reprodu	ctive. Ah	domina	l and		
Note 10 STIC Color (New)			ological Device		~viiiiii	- 4114		
Prescription Use Only (Pcr 21	CRF801.109)		k) Number	Ko	916	195	>	pain.